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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,804	06/20/2001	Lea Eisenbach	EISENBACH 3	6094

1444 7590 08/10/2005

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WASHINGTON, DC 20001-5303

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/744,804	<b>Applicant(s)</b> EISENBACH ET AL.	
	<b>Examiner</b> MISOOK YU, Ph.D	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16 and 55-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 55-57 is/are allowed.
- 6) ☒ Claim(s) 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 16, and 55-58 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112, Maintained***

Claim 58 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NOs: 35-41, does not reasonably provide enablement for other peptides consisting of 9 or 10 contiguous amino acid residues in the sequence of SEQ ID NO: 78. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that the specification guides one of skill in the art a software (available through world wide web) selecting which peptides would bind to MHC class I type molecule. The software based on accumulated data scores every possible peptides in the protein for possible binding to MHC according to the contribution of every amino acid in the peptide. Therefore binding scores present calculated half-life of the HLA-A2-peptide complex. Applicant further argues that after computer software aided selection of the MHC class I molecule binding peptides, in vitro cytotoxicity assay is performed as described in the specification. Those seven peptides that work were selected from this selection process disclosed in the specification. Thus, other peptides with a different affinity can be predicted and synthesized or modified and used for the purpose of the present invention according to the procedure described in the

specification. Therefore, those of skill in the art are enabled for the full scope of the claimed invention.

These arguments have been fully considered but found unpersuasive. As stated in the previous Office action, the specification at Fig. 15-17 discloses that instant SEQ ID NOs:35, and 38 work best to promote effective binding to a MHC class 1 type molecule so as to elicit a CTL response while BA46-8 shown at Fig. 16 does not work as well as other peptides from the instant SEQ ID NO:78, which is 387 amino acids in length. This means there are numerous, in fact, over 1,000 different 9 or 10 contiguous amino acid residues peptide sequences could be generated from the instant SEQ ID NO:78. However, the specification does not disclose common structural attributes that promote effective binding to a MHC class 1 type molecule so as to elicit a CTL response. This indicates that one has to determine experimentally which one of the over 1,000 different peptides could work to promote effective binding to a MHC class 1 type molecule so as to elicit a CTL response.

US Pat. 5,840,839 (Nov. 24, 1998, cited in the Office action mailed on 3/13/2003) is again cited here to make a point that selection of peptides using a computer algorithm does not always work. US Pat. 5,840,839 teaches at column 19 that finding a peptide that binds to a MHC molecule and stimulates immune response is not a trivial matter. In other words, the '839 patent at column 19, lines 53 to 67 teaches that structure a T cell epitope that stimulates immune response in context of MHC molecules is unpredictable in the current state of art. The '839 patent at columns 19-20, and Table 1 teaches that the various candidate T cell epitopes selected based on theoretical

binding motif (using computer algorithm) of one class of MHC molecule, i.e. HLA-A31 do not work when they are experimentally tested as shown in Table 1. This suggests that theoretically selected T cell binding motifs have to be tested experimentally in order to determine whether they are actually T cell epitopes or not.

Considering the unpredictable state of art, limited guidance, the broad scope of the claims in terms of both the structural nature of the peptides as well as the nature of MHC molecule being claimed, it is concluded that undue experimentation is required to practice the full scope of the claimed invention.

***Allowable Subject Matter***

Claims 16, and 55-57 are allowed.

***Conclusion***

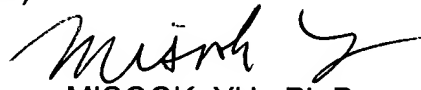
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MISOOK YU, Ph.D  
Examiner  
Art Unit 1642